Direct to You: TV Drug Ads *That Make Sense*

The secret's out. The prescription drug Claritin is an antihistamine for seasonal allergies, new TV commercials reveal. Before August 1997, the Claritin television ads said little beyond, "At last, a clear day is here," and "It's time to see your doctor."

Not much to go on in those earlier ads, and the commercials for Claritin's main competitor, Allegra, were equally unrevealing. Why the secrecy? Because, by stating the drug's name but not what it was used for, the ads were exempt from a Food and Drug Administration regulation that generally requires prescription drug advertisements to disclose the risks of the medication as well as its benefits. From the drug companies' perspective, it was impractical to include detailed risk information in a 30- or 60-second TV spot.

But the so-called "reminder ads" for Claritin and other drugs left consumers puzzled. "We used to get a tremendous amount of phone calls saying, 'What is Claritin? What is it for?'" says Alex Giaquinto, senior vice president for worldwide regulatory affairs for Schering-Plough Corp., the drug's manufacturer. "You'd be surprised. We got calls from gynecologists saying patients were asking if they were candidates for Claritin."

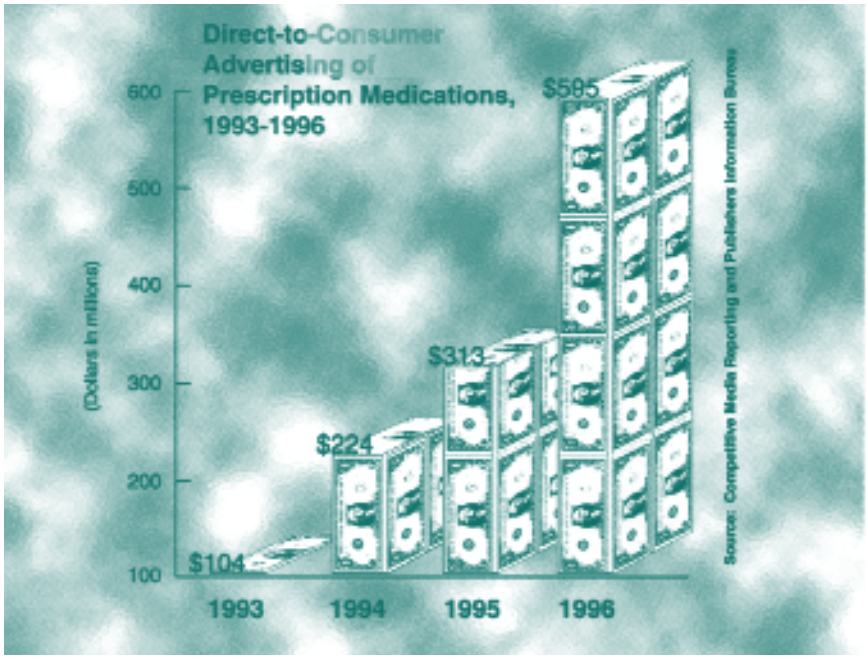
In part, because of the consumer confusion and concerns that some TV and radio advertisements might be misleading, FDA reviewed its policies on broadcast ads and, in August 1997, issued a draft guidance for public comment. The new guidance describes how prescription drug companies can advertise a product directly to consumers on TV or radio, including the product's use, without scrolling the type of detailed risk information that accompanies magazine and other print advertisements.

The makers of Claritin and Allegra soon began airing revised ads. "Only one tablet means 24-hour, nondrowsy seasonal allergy relief," announced the new Schering-Plough commercial.

Not everyone agrees that these "direct-to-consumer" ads are beneficial. At a 1995 public hearing on consumer-directed advertising, FDA heard from scientists, drug companies, patient advocates, and medical professionals. Some objected to direct-to-consumer ads, saying that they mislead consumers because they don't provide a complete picture of the drug. Others favored the ads, telling the agency that a consumer-directed ad can be an important educational tool in an era when patients want to be more involved in their own healthcare.

But, says Nancy Ostrove, chief of marketing practices and communications in FDA's division of drug marketing, advertising, and communica-

Before August 1997, many TV commercials for prescription drugs stated little more than the product's brand name and "ask your doctor" (left). Now, drug companies are airing TV commercials that tell viewers not just the name of the drug, but also the medical condition it is used to treat (right). Source: Schering Corp.



tions, "Direct-to-consumer advertising is not inherently bad or good. It can be useful or harmful, depending on how it's done."

Truth in Advertising

FDA has regulated the advertising of prescription drug products since 1962, under the Federal Food, Drug, and Cosmetic Act and related regulations. Most other advertising, including the advertising of over-the-counter drugs, is regulated by the Federal Trade Commission, under a different set of rules.

FDA generally interprets the term "advertisement" to cover information other than labeling that promotes a product. The term includes promotions broadcast on television or radio, conducted by telephone, or printed in magazines or newspapers. (See "Drug Promotion in Cyberspace," p. 77.)

For many years, prescription drug makers promoted their products exclusively to healthcare professionals. But about 15 years ago, some manufacturers began to produce ads targeted to consumers.

Since then, direct-to-consumer advertising has become a popular promotional tool. In 1996 alone, prescription drug manufacturers spent almost $600 million on this type of advertising, according to Competitive Media Reporting, which projected 1997 spending to be at least twice that.

And consumer-directed ads seem to be capturing consumers' attention. In a 1996 study by drug industry consultant Scott-Levin, three-quarters of the doctors surveyed said their patients have talked about drug ads they heard or saw.

FDA regulates consumer-directed ads under the same regulations as professional-directed ones. Like promotions directed to healthcare providers, consumer ads may only make claims that are supported by scientific evidence and that are not inconsistent with the FDA-approved product labeling. And, like professional-directed advertisements, they may not be false or misleading.

FDA oversight helps ensure that consumers understand both the benefits and limitations of an advertised drug. (See "In Trouble with FDA," p. 76.) The agency monitors ads to make sure they are tailored for the target audience. For example, a consumer-directed ad may be considered misleading unless it explains the drug's benefits and risks in words that people who aren't medical professionals can understand.

FDA regulations call for "fair balance" in every ad. FDA reviewers look at the entire advertisement to see if it is balanced. The risks as well as the benefits must be clearly identified, and the risks must be presented prominently and readably so that the benefits are not unfairly emphasized.

Under the Federal Food, Drug, and Cosmetic Act, most ads must include a "brief summary" describing the effectiveness of the drug and its risks. In print ads, drug companies usually meet the requirement by including entire risk-related sections of the approved labeling. Many people have expressed concern to FDA that, because drug labeling is primarily written for doctors, much of it cannot be understood by consumers.

"The brief summary might be fine for someone who went through medical school," says Linda Golodner, president of the National Consumers League. Even then, she says, "you have to get out a magnifying glass to try and sort out the information."

FDA is considering what steps can be taken toward a more consumer-friendly format. In the meantime, says Ostrove, "We encourage manufacturers to write the brief summary information to be more understandable to consumers."

TV Reality

In a short television or radio ad, manufacturers have found it difficult to meet the brief summary requirement. "Scrolling a long, detailed brief summary on a television screen is not practical on commercial television," writes drug law expert Wayne Pines in the Thompson Publishing Group's *Advertising and Promotion Manual*.

So, for television commercials and sometimes print ads, companies have historically opted for two types of ads —"reminder" ads and "help-seeking" ads—that are exempt from the brief summary requirement.

Reminder ads, like the original version of the Claritin commercial, call attention to a drug's name, but don't state the condition it is used to treat.

Help-seeking ads tell consumers only that there are treatments available for a particular condition and encourage them to talk to a health-care professional. To be considered a help-seeking advertisement, an ad may not state or imply the name of a particular product, although it can mention the manufacturer's name. One such magazine ad said simply, "Life without ulcers. It is now possible. See your doctor."

The reminder and help-seeking ad "each has only part of the information a consumer wants, which can create a lot of confusion," Ostrove says.

Completing the Puzzle

FDA regulations have always permitted sponsors of television and radio ads to present a brief summary. Or, instead, they could make "adequate provision" for interested people to get the approved labeling.

Before August 1997, FDA had not described "adequate provision" for consumer-directed ads, so drug companies were not taking advantage of the option because they were uncertain about whether their ads would meet FDA's standards.

The draft guidance doesn't change the regulation, but rather describes one way to meet the requirement. Under the approach described in the guidance, "adequate provision" is accomplished if the ad contains the following:

- a toll-free telephone number so consumers can request the approved package labeling by mail, fax, or prerecorded telephone message;
- a reference to print ads about the product in consumer magazines so consumers can read more detailed drug information, or to brochures containing the package labeling that a consumer can find conveniently in public places such as libraries, pharmacies, doctors' offices, and grocery stores;
- a statement that additional product information is available from a doctor or pharmacist; and
- an Internet address where package labeling can be found.

Whether the brief summary or "adequate provision" is used, however, the most important risk information must always be included in the ad itself. This information is often referred to as the "major statement."

Joint Responsibility

Some consumer-directed ads can raise awareness that drugs are available to treat certain conditions, including diseases such as seasonal allergies that might not require a doctor's care, and undertreated conditions such as depression and impotence. "We have a huge patient population for which there are drugs available to help them live longer and better lives," says John Kamp of the American Association of Advertising Agencies. He adds that government agencies and medical professionals "can use their tools until they're blue in the face and not reach the people who will be reached through television."

While a doctor's prescription is necessary to get these medications, some at the 1995 public hearing expressed a concern that this alternative source of drug information would interfere with the doctor-patient relationship. The National Consumers League's Golodner and others, however, feel that consumers will communicate with their physicians more, not less, if they are aware that a drug exists for their condition.

In Trouble with FDA

Generally, FDA does not require preclearance of promotional materials. But the agency often reviews drug companies' draft promotional materials at their request.

If FDA finds that company's advertisement is false or misleading, the agency may take enforcement action against the company. The agency regulates all of a drug company's prescription drug promotions, including the promotional tactics of its salespeople.

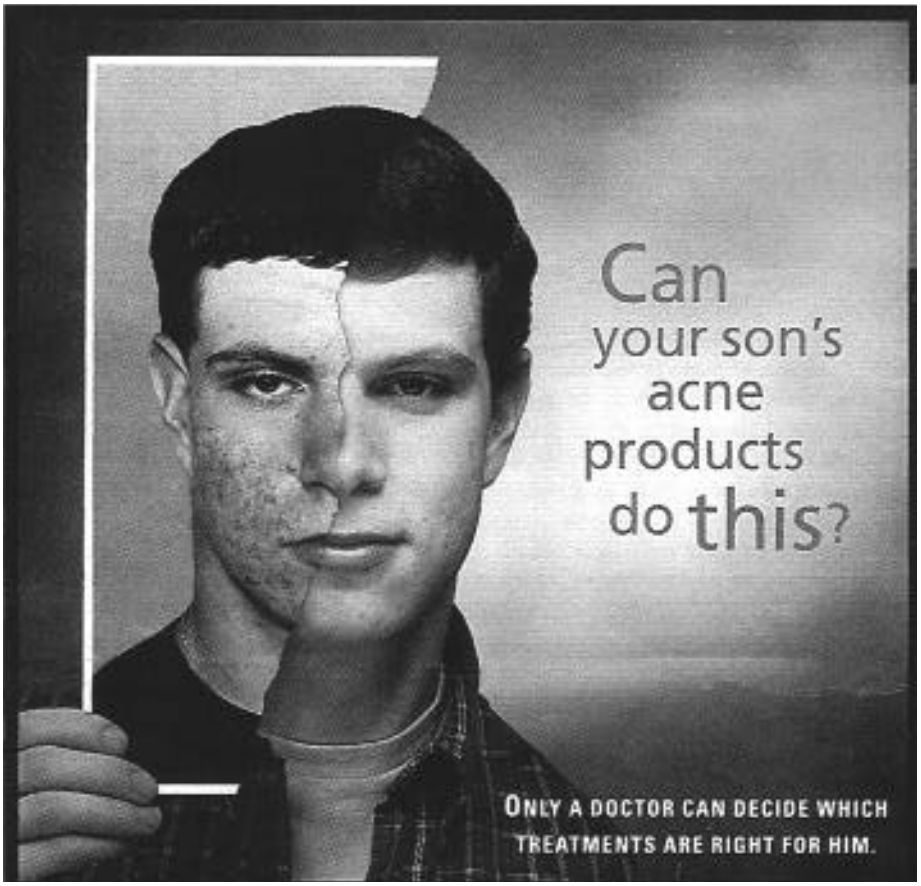
For the least serious violations of advertising regulations, FDA will send the drug company an "untitled letter" outlining the agency's findings.

For more serious violations, FDA may issue a "warning letter" requesting that the company immediately stop the violative advertising and, in many cases, take other corrective steps.

For example, the company may be asked to send a "Dear Doctor" letter to alert those who prescribe the medication to FDA's finding. The company may also be asked to run corrective advertisements setting forth FDA's concerns and bringing the ad's language into compliance. Finally, a warning letter may request that a company send its future promotional materials to FDA for clearance before they are used.

Beyond sending untitled letters and warning letters, FDA may stop violative promotions by seizing affected products or enjoining the use of promotions that make the same or similar claims. These actions and the most serious remedy, criminal prosecution of the company or the individuals involved, are used rarely—generally when intentional and serious misstatements are involved.

The threat of agency action isn't the only thing that keeps companies honest, says John Kamp of the American Association of Advertising Agencies. "A drug company won't play fast and loose with the rules because its most important asset is its reputation with the American people."



"In healthcare," Golodner says, "there is a general trend toward having consumers more responsible for their own health. Now, consumers can go to their physicians with a little more information."

A related issue raised at the 1995 public hearing is whether such ads would lead to patients pressuring doctors to prescribe unneeded medications. Many speakers emphasized the doctors' duty to advise their patients responsibly. Mary Jane Sheffet, from Michigan State University's marketing department, told FDA, "The doctor needs to be there as a gatekeeper."

With the health concerns of both supporters and opponents in mind, the agency continues to review its policies on direct-to-consumer promotion. As more ads have been reviewed by FDA, Ostrove says, the agency "has become more and more confident that the appropriate information, including risk information, can reach consumers and be helpful to them."

But the foremost goal of advertisers will always remain the same: to get people to use their products. So Ostrove urges consumers to regard prescription drug ads with careful consideration.

"These are prescription drugs with real potential downsides," she says. "We don't want people going to their doctors and saying, 'I want this drug.' The message should be, 'I saw this ad. Is it right for me?'"

Drug Promotion in Cyberspace

Like many other companies, prescription drug marketers are beginning to take advantage of the extensive reach of the Internet to promote their products. FDA monitors the Internet to check the quality of the information provided, and encourages consumers to remain vigilant to separate the good information from the bad. (See "Health Information On-Line" in the June 1996 *FDA Consumer*.)

"Generally, FDA is treating Internet promotion like it does other forms of promotion," says Melissa Moncavage, a public health advisor with FDA's division of drug marketing, advertising, and communications. "Although the Internet is brand new, the promotion content issues are largely the same as print, broadcast, and other traditional media."

To address those issues that are unique to the Internet, FDA held a public meeting in October 1996 to hear from consumers, patient groups, health professionals, manufacturers of FDA-regulated products, and others.

The questions discussed at the meeting included:

- Where should promotional product information be located on a company's Web site?
- How can promotional information on the Internet be clearly distinguished from other information?
- How can Internet users be assured access to a balanced presentation of risks and benefits?
- Should Web sites distinguish between Internet promotions directed to health professionals and consumers? How?
- How should the promotional materials of multinational companies be addressed to ensure compliance with U.S. drug laws and regulations?

Also, in a Sept. 16, 1996, *Federal Register* notice, FDA requested written comments on some of these same Internet-related drug promotion issues. The agency is considering the written comments, suggestions of meeting participants, and information received since the meeting, and plans to publish a guidance to clarify its policies.